EXHIBIT 10

August 31, 2017

I. Introduction

This report supplements my expert report dated October 1, 2014, and the first supplemental report dated June 19, 2015.

II. Human Drugs that Cause Birth Defects: Thalidomide, Accutane, Valproic Acid

I have been asked where I would place Valproic Acid on the severity scale of drugs that cause human birth defects. I have testified that, excluding drugs that are used to treat cancer, the top three are thalidomide, Accutane, and valproic acid.

As a physician, epidemiologist, teratologist and geneticist who has since 1968 focused on preventing birth defects from all causes, it is natural for me to consider drugs as possible causes of birth defects, to conduct or supervise studies seeking to find causes of birth defects, to evaluate other studies of possible causes of birth defects, and to interpret them and make policy recommendations to prevent or reduce the risk from known causes of human birth defects. My lifelong work as a teratologist, epidemiologist and geneticist has given me many opportunities to learn about the causes of birth defects and how dangerous certain drugs are. My long professional life time of evaluating potential causes of birth defects has taught me that, in rating a drug's importance in causing a birth defect, one should consider the following:

1. How certain can one be that the drug causes birth defects?

2. How severe are the birth defects?

3. Does the drug cause other problems, like mortality, decrease in cognitive performance, autism or prematurity?

4. What is the relative risk or odds ratio from the exposure?

5. What is the rate of disease after exposure?

6. How many children have been affected?

There are few drugs proven to cause birth defects in human beings. Although there are thousands of drugs approved for marketing in the United States, only a relative few are known to cause birth defects. Shepard and Lemire and Holmes have published comparable lists of about 20 drugs that are known or likely to cause birth defects in human beings.[1] [2] Both of these lists include thalidomide, Accutane (isotretinion (13-cis-retinoic acid), and valproic acid as known human teratogens.

Thalidomide is an example of a drug that was safe and effective in the mother, but caused catastrophic damage to the embryo/fetus.[3] This problem resulted in a search for existing drugs that might cause birth defects and surveillance systems with the mission to identify, as soon after marketing as possible, any new drugs that cause birth defects in people. For example, our work at the CDC included a case control study to evaluate two widely used drugs, Valium and Bendectin. We found an association in a study in the late 1970s that suggested Valium may cause a facial cleft.[4] The manufacturer, Hoffman-La Roche, then supported a research epidemiology group in Boston to use their surveillance system to conduct

a case control study to investigate the hypothesis. I was appointed to their review committee. In a well-designed study, they did not confirm the association.[5] Our study of Bendectin in Atlanta identified no association with birth defects.[6] These are examples of drugs that were thought to cause, or perhaps cause, birth defects that have joined the large group of drugs that are not known to cause birth defects.

A. Thalidomide is a Major Cause of Birth Defects

The sleeping pill/anti-nausea drug thalidomide was marketed in Germany in the late 1950s and was recognized in late 1961 as the cause of a major epidemic of birth defects in Germany and many cases in the United Kingdom and Japan.[3] These birth defects included a striking, almost unique shortening of the long bones of legs and forearms. (A single photograph would make it very clear how much damage this drug could cause a baby.) It was this unusual and very rare birth defect that was very important in identifying thalidomide as the cause of the epidemic. A German geneticist, who had seen several cases, discovered the cause was thalidomide. A newspaper account of his findings led to a drop in sales followed by the drug company's removing the drug from the market.[3]

Although the epidemic of drug induced birth defects was largest and most apparent in Germany, it was almost universally seen as a great failure in public policy. It has been estimated that 10,000 children were affected by the drug before it was learned that it caused these serious birth defects.[3] The prompt removal, once thalidomide was known to cause birth defects, stopped birth defects from occurring. Although the drug has been reintroduced into the United States market, it is marketed with a very strong program designed to minimize the

chance that pregnant women would be exposed called REMs (formerly known as the S.T.E.P.S. program).[7] For example from the Black Box Warning: "Warning: Severe, Life-threatening Human Birth Defects." "If thalidomide is taken during pregnancy, it can cause severe birth defects or death to an unborn baby." In addition, for female patients, it warns that use is inappropriate unless: "she acknowledges...the need for two reliable methods of contraceptive 4 weeks prior to beginning thalidomide therapy, during thalidomide therapy, and for 4 weeks after discontinuing of thalidomide therapy."[8]

Thalidomide also makes the point that continues to today: drugs that are approved for marketing have seldom been tested in women who are or who might become pregnant. Had there been a pregnancy registry following the first 1000 women exposed to thalidomide, it is likely that this tragic epidemic would have been discovered earlier, and fewer than 10,000 babies would have been affected. Thankfully, the United States did not have an epidemic as the drug was never approved by the FDA. Dr. France Kelsey was the physician pharmacologist who did not approve the drug and prevented thousands of American children from these birth defects. For her work, she received from President Kennedy the Presidential Medal of Honor.

Given the explosive nature of the thalidomide epidemic, given the certainty that thalidomide causes birth defects, given the severity of the life threatening and life altering birth defects, given the 10,000 children affected, and given the impact on drug regulations world-wide, I conclude that thalidomide is one of the top three drugs that cause birth defects in human beings.

B. Accutane Proved To Be a New Major Human Teratogen in Early 1980s

Vitamin A and retinoic acid were known to cause birth defects in animals including monkeys. It was therefore assumed that Accutane (13-cis-retinoic acid), a powerful vitamin A compound, would also cause birth defects in human beings.[9] The FDA permitted this likely human teratogen to be marketed because it appeared especially effective in cystic acne--a disease that primarily afflicted males. Its package information noted it likely would cause severe birth defects, and no woman of reproductive age should take the drug without taking contraceptives. The company increased its warnings against pregnancy and instituted a program to reduce the likelihood of the drug causing birth defects. For example, the Accutane Black Box Warning of 2006 warned: "CONTRAINDICATIONS AND WARNINGS" "Accutane must not be used by female patients who are or may become pregnant."[10] "Accutane must only be dispensed to patients who are registered AND meet all the requirements of iPLEDGE..." iPLEDGE includes many requirements designed to minimize pregnancy, such as women of reproductive age must have two negative separate pregnancy tests before being able to receive the first prescription.[11]

Unfortunately, there were exposed fetuses. I recall being told about a baby with severe facial, ear and heart malformations who later died from complications of the surgery to try to repair the heart defect. Dr. Ed Lammer and I visited the hospital to see the infant. Soon, Dr. Lammer showed me a reprint of a monkey treated with the drug that had remarkably similar facial defects. I concluded, based on this one case, that we had a new, major cause of birth

defects to add to the list of drugs that cause birth defects. I assigned Dr. Lammer to set up a registry to learn more about the birth defects this drug could cause. He worked several years on this, including a fellowship supported by La Roche. His findings, reported in the New England Journal of Medicine, remain a classic study demonstrating that Accutane is a powerful cause of severe, life-threatening human birth defects.[12] The certainty that the drug causes human birth defects, the high relative and absolute risk of birth defects following exposure, and the severity of the birth defects that were often fatal provide ample justification for me to conclude that this drug is one of the three most important drugs that causes birth defects.

C. List of Drugs Proven To Cause Birth Defects in Humans Is Limited

Once it was known that thalidomide, a drug that was thought to be safe for adults, was shown to cause birth defects, many thought that other marketed drugs would be found to cause birth defects. There have been few other non-cancer treatment drugs shown to cause birth defects. Shepard and Lemire and Holmes list about 20 non anti-cancer treatment drugs that cause human birth defects. None of these other drugs would I conclude are as important or potent in causing human birth defects as thalidomide, Accutane and valproic acid. For example, Tetracycline and doxicillin cause a minor discoloration of the teeth, not life threatening birth defects. While nice not to have, stained teeth seem almost trivial compared to the birth defects caused by thalidomide, Accutane or valproic acid. There are relative old weak data that lithium causes a rare heart defect called Ebstein's Anomaly. A more recent study shows that the early data were poor and overestimated the possible risk.[13] It is a very serious birth defect, but the quality of the old data and the new data suggests lithium is a less

important cause of human birth defects than thalidomide, Accutane or valproic acid. The other drugs on the lists, while known to cause birth defects, do not have reported data that would merit their being in the top three most important non-cancer drugs that cause birth defects.

D. Thalidomide, Accutane, and Valproic Acid Are the Most Powerful, Most Important Non-Cancer Treatment Drugs in Causing Birth Defects

Thalidomide, Accutane, and valproic acid all cause life altering, life threatening birth defects, a fact based not just on my observations from decades of studying birth defects, but also on the scientific data. Above in this report I have discussed data that support my conclusion that Accutane and thalidomide are in the top three most potent non anti-cancer drugs that cause human birth defects. I have testified that valproic acid is one of the top three most potent non anti-cancer drugs that cause birth defects in human beings.[14-18] Note that even if one assumed that valproic acid causes only spina bifida, in my opinion it qualifies as one of the three most important drugs that cause human birth defects. We are certain that valproic acid not only causes spina bifida, but also increases the risk of major malformations by at least threefold, that it increases the chance of reduced cognitive functioning, and ever increasing evidence that it is a cause of autism.[19] There is no accurate count of the number of babies in the world that have developed birth defects because of valproic acid or how many fetuses were aborted because the mother learned the baby had spina bifida. The expansion of the indication for valproic acid from epilepsy to migraine headaches and psychiatric indications increased the number of women of reproductive age and their embryos exposed to valproic acid. Given that the drug has been continuously marketed worldwide since the 1970s, it is likely that more babies have adverse effects from in utero exposure to valproic acid than babies have had

adverse effects from in utero exposure to thalidomide or Accutane. In my opinion, whatever the actual numbers of fetuses that have damaged by valproic acid around the world, the number is likely to have been less if the indications for the drug had not been expanded to migraine headaches and psychiatric indications and if the company had developed and implemented comprehensive programs, like those developed by the manufacturers of thalidomide and Accutane, designed to minimize the number of pregnancies exposed to valproic acid. Not only did Abbott fail to institute appropriate studies or registries to evaluate valproic acid as a cause of adverse health and developmental problems for babies exposed in utero, but also it is my opinion that Abbott should have instituted programs similar to Ipledge and REMS - those undertaken by the manufacturers. Such a program would likely have reduced the number of children adversely affected by in utero exposure to valproic acid.[7, 11]

IV. Supplemental Disclosures

Since my June 19, 2015 supplemental report, I have testified, in deposition or trial, in the following matters:

J.F. v. Abbott Laboratories Inc., 14-cv-847, In the United States District Court for the Southern District of Illinois (deposition);

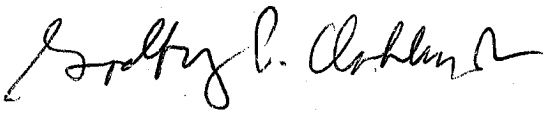
B.F. v. Abbott Laboratories Inc., 4-12-cv-01760-CAS, In the United States District Court for the Eastern District of Missouri (trial);

Z.H. v. Abbott Laboratories Inc., 1:14-cv-00176-CAB, In the United States District Court for the Northern District of Ohio (deposition and trial by video);

H.B. v. Abbott Laboratories Inc.; T.C. v. Abbott Laboratories Inc.; E.R.G. v. Abbott Laboratories, 12-cv-52; 15-cv-702, In the United States District Court for the Southern District of Illinois (deposition);

E.R.G. v. Abbott Laboratories Inc., 15-cv-55; 15-CV-702, In the United States District Court for the Southern District of Illinois (trial).

Respectfully,



Godfrey P. Oakley, Jr., M.D., M.S.P.M.

Research Professor, Department of Epidemiology

Director of Center for Spina Bifida Research, Prevention and Policy

The Rollins School of Public Health of Emory University

Citations

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13. Patorno E, Huybrechts KF, Bateman BT, et al. Lithium Use in Pregnancy and the Risk of Cardiac Malformations. *N Engl J Med* 2017;376:2245-2254.
14. Testimony of Dr. Oakley from the Schmidt v. Abbott Laboratories Trial (Cause No. 1222-CC02479-01) see Transcript on Appeal at 504:14-22
15. Testimony of Dr. Oakley from the Forbes v. Abbott Laboratories Trial (Cause No. 4:12-cv-1760-CAS) see Transcript, Vol. 2B at 22:15-19
16. Testimony of Dr. Oakley from the Raquel v. Abbott Laboratories Trial (Cause No. 15-cv-702-NJR-SCW) see Transcript at 271:10-272:24
17. Testimony of Dr. Oakley from the 4/26/16 Deposition of Dr. Oakley related to the Raquel v. Abbott Laboratories case (Cause No. 15-cv-702-NJR-SCW) see Transcript at 12:14-22, 13:12-14:5
18. Testimony of Dr. Oakley from the 8/4/15 Deposition of Dr. Oakley related to the Leal v. Abbott Laboratories case (Cause No. 14-cv-847-NJR) see Transcript at 217:3-225:9.
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